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EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 02/26/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/712,615

Applicant(s)

BUECHLER ET AL.

Examiner

Lisa V. Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27,28 and 93-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27,28 and 93-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. Applicants' response to the Office Action mailed August 24, 2001 (Paper #11 filed 12/6/01) is acknowledged. In response to amendment-A filed therein, the specification along with claims 27 and 28 were amended. Claims 27-28 and 93-108 are pending and under consideration.

OBJECTIONS WITHDRAWN

Priority

2. The specification has been updated to include the following: " This application is a continuation of Application No. 09/003,065, filed on January 5, 1998, now Patent #6,194,222". Therein this objection is withdrawn.

Drawings

3. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 12/6/01 were stamped approved by the Draftsperson under 37 CFR 1.84 or 1.152.

Specification

4. The supplemental specification filed 12/6/01 has corrected the following citings:

I. The disclosure is objected to because of the following informalities: The specification utilizes an invalid patent application no. on page 53, line 14 "96/05476". Please correct.

II. The application papers are objected to because they are not a permanent copy as required by 37 CFR 1.52. Reference is made to illegible portion(s) of pages 71, 72, 78, line 30 and page 88 – left margin, in all instances appears to be cut off during photocopying.

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Applicant is required either (1) to submit permanent copies of the identified parts or (2) to order a photocopy of the above identified parts to be made by the Patent and Trademark Office at applicant's expense for incorporation in the file. See MPEP § 608.01.

III. The disclosure references several U.S. Application nos. and in some instances only gives the title of the Applications. For example, see page 1, lines 7-13 and page 29, lines 22-30. The title is insufficient in identifying the applications because several applications may employ the same title. The application number should also be included. Further, some of the applications have been patented and should be updated to include the U.S. patent numbers (08/458,276 now Patent #5,922,615 – 08/065,528 now abandoned – 08/447,895 now Patent #6,019,944 – 08/274,534 now 6,238,931). It is suggested that the disclosure be update include the appropriate application numbers and/or patent numbers.

IV. The use of the trademarks has been noted in this application. (i.e. SMCC, SPDP - pages 52 and 57). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

The specification is withdrawn from objection.

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Claim Objections

The amendments to claims 27 and 28 have corrected the claims, they are withdrawn from objection.

5. Claims 27(c) and 28(iii) are in improper markush format. "at least one of" should be "selected from the group consisting of". See MPEP 2173.05(h) Alternative Limitations.

6. In claim 28 the duplicate use of (a) and (b) is misleading. The claims should be numbered consecutively as not to provide uncertainty in the limitations. It is suggested that applicant utilize different symbols. [i.e A, B and (a), (b)].

OBJECTIONS MAINTAINED

Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

8. The information disclosure statements filed 6/25/01-Paper #6, has not been considered as to the merits prior to first action because the Information Disclosure Statement under 37 CFR 1.56 was not signed. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

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Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Applicant contends that the Information Disclosure Statement was previously submitted in the parent application and should therefore be considered by the examiner without a signature. This argument was carefully considered but not found persuasive because 37 CFR 1.1-2(b) requires a signature for each file. The objection is maintained.

Since each file must be complete in itself, a separate copy of every paper to be filed in a patent or trademark application, patent file, trademark registration file, or other proceeding must be furnished for each file to which the paper pertains, even though the contents of the papers filed in two or more files may be identical. The filing of duplicate copies of correspondence in the file of an application, patent, trademark registration file, or other proceeding should be avoided, except in situations in which the Office requires the filing of duplicate copies. The Office may dispose of duplicate copies of correspondence in the file of an application, patent, trademark registration file, or other proceeding.

REJECTIONS WITHDRAWN

Double Patenting

9. Double patenting obviousness-type rejection:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

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See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 27, 28, and 93-108 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-22 of U.S. Patent No. 6,194,222. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are drawn to devices wherein progress and time of completion of an assay are measured with a device comprising a reaction chamber and at least one diagnostic reaction chamber having a label.

Although the instant application is directed to “a processor for determining the process and time of completion” as it relates to the assay. This invention is encompassed within Patent #6,194,222 wherein a device determines progress and time of an assay. Patent #6,194,222 encompasses the instant invention, wherein the method uses the instant device.

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It would have been obvious to the skilled practitioner in the art to employ various determining evaluations/modifications and track such signals, as it would relate to determining assay progress and time of completion in an assay device.

Response to Arguments

Applicant contends that the instant application is a continuation of Application No.09/003,065 and was subjected to a restriction requirement during prosecution. Therefore a double patenting rejection is not permitted. This argument was carefully considered and found persuasive, the rejection is withdrawn.

Claim Rejections

11. With respect to the claim rejections under 35 U.S.C. 102 and 35 U.S.C. 103, Applicant argues that the references do not specifically recite and optical component configured to receive electronic signals. Applicant's arguments have been fully considered and found persuasive.

12. The following rejections are withdrawn:

I. Claims 27, 93, 94, 96, 97, 98, 99, and 100 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheppard et al. (U.S. patent #6,143,247).

II. Claims 27, 93, 94, 96, 97, 98, 99, and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U. S. Patent #5,458,852) in view of Van Deusen et al. (U.S. Patent #5,132,097).

III. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al. (U.S. patent #6,143,247) or Buechler (U. S. Patent #5,458,852) in view of Van Deusen et al. (U.S. Patent #5,132,097) in further view of Slovacek et al. (U.S. Patent#5,242,837).

IV. Claims 28 and 101-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al. (U.S. patent #6,143,247) or Buechler (U. S. Patent #5,458,852) in view of Van Deusen et al. (U.S. Patent #5,132,097) in further view of Slovacek et al. (U.S. Patent#5,242,837) as applied to claims 27 and 93-100 above, and further in view of Zuk et al. (U.S. Patent#4,281,061).

REJECTIONS MAINTAINED

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 28 and 101-108 remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: kit components/reagents, which would include positive limitations with respect to kit. Presently the claims merely read on an apparatus/device. Instructions are not patentable in a kit wherein the kit only contains the apparatus. Applicants should note that the printed matter on the instructions in a kit cannot serve to define the kit over the prior art. See *in re Gulack* 217 USPQ (CAFC 1983).

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 27, 93, 94, 96, 97, 98, 99, and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U. S. Patent #5,458,852) or Sheppard et al. (U.S. patent #6,143,247) in view of Van Deusen et al. (U.S. Patent #5,132,097).

Buechler discloses assay devices meeting the requirements of the instant invention. This is supported by the specification on page 59, lines 21-28. Particularly Buechler's device comprises a reaction chamber having a diagnostic lane. See figures 1-5, item #4 (reaction chamber, column 6 and 7), item #17 (optional reagent chambers, column 8 and 9, and item # 6 (diagnostic element, column 10). The device is useful in measuring an absolute signal or a rate of change of the signal. Particularly determining the presence or amount of each target ligand in the sample either visually or instrumentally. Column 17, lines 44-46. The rate of change is monitored via the flow rate of reagents through the porous member. Column 18, lines 2-9. Further the label (signal development element) does not appreciably bind to any reagent in said assay device but could be designed to indirectly cause a visually or instrumentally detectable signal as a result of the assay process. Column 3, lines 17-25.

Although the reference is silent with respect to the intended use of the apparatus (measuring progress and time of completion for an assay), the claimed functional limitation would be inherent property of the referenced device. The apparatus is the same irrespective of what its intended use is. *In re Casey*, 152 USPQ 235 (CCPA 1967).

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Sheppard et al. disclose an affinity-binding based analytical apparatus comprising a platform (device) with a specific binding reagent deposited on the surface of the chamber. Column 3, lines 16-22. A reaction chamber (binding chamber) in Figure 3A, 34 - having distinct specific binding reagents comprising diagnostic lanes (first members of binding pairs deposited thereto) in figures 3F, 3G, and 3H, 34 are taught. The apparatus further has a means for detecting optical signals generated from specifically bound particles in the surface or chamber. Column 3, lines 45-67. The label does not appreciably bind to any reagent in the assay device but can be configured to bind the analyte of interest or test compound that is introduced into the device for analysis. See column 3, lines 56 (labeling reagents may specifically bind the particulates accumulated in the detection chamber), column 3, lines 58-65 (labeling reagents are attached to 1st and 2nd binding pairs that indirectly detect the unknown), and column 4, lines 61-67 through column 5, lines 27 (labeled reagents bind a reaction product produced via an test compound introduced into the device). Finally the device includes a signal processor (detector or optical heads). See column 11, especially lines 33-44.

Although the reference is silent with respect to the intended use of the apparatus (measuring progress and time of completion for an assay), the claimed functional limitation would be inherent property of the referenced device. The apparatus is the same irrespective of what its intended use is. *In re Casey*, 152 USPQ 235 (CCPA 1967).

Buechler and Sheppard et al. differ from the instant invention in not disclosing the device with an optical component and a signal processor specifically configured to generate and read electronic signals.

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However, Van Deusen et al. teach devices having both an optical signal detector and signal processor. Van Deusen et al. disclose an apparatus for analyzing specific binding complexes. A test strip having a reactive surface coated with a specific binding member is employed and laser analysis allows for detection via a detector assembly (processor). See abstract, Column 2, 55-68 through column 3, lines 1-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure optical signals via a signal processor as taught by Van Deusen et al. in the device of Buechler to perform immunoassay detection procedures, because such signal and processors as taught by Van Deusen et al. were well known in the art at the time of the instant invention. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing such systems, because Van Deusen et al. taught that signal processors allowed for information gathering and dissemination. (Column 3, lines 33-35).

One having ordinary skill in the art would have been motivated to do this to greatly reduce the time required for analysis. Column 3, lines 20 -21.

II. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al. (U.S. patent #6,143,247) or Buechler (U. S. Patent #5,458,852) in view of Van Deusen et al. (U.S. Patent #5,132,097) in further view of Slovacek et al. (U.S. Patent#5,242,837).

Please see Sheppard et al. as set for in item 16 above. Buechler (U. S. Patent #5,458,852) in view of Van Deusen et al. (U.S. Patent #5,132,097) are set forth in item I above.

The primary references do not particularly exemplify the use of a fluorometer as a useful optical detector.

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However, fluorometers are routinely utilized to detect specific binding reagents. This point is supported in the patent of Slovacek et al. Therefore the use of a fluorometer is routine optimizations that are almost always determined and used in immunoassay studies. Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different known detectors in the given parameters to determine the unknown as a means of optimizing the device provided by the art.

III. Claims 28 and 101-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al. (U.S. patent #6,143,247) or Buechler (U. S. Patent #5,458,852) in view of Van Deusen et al. (U.S. Patent #5,132,097) in further view of Slovacek et al. (U.S. Patent#5,242,837) as applied to claims 27 and 93-100 above, and further in view of Zuk et al. (U.S. Patent#4,281,061).

The teachings of Sheppard et al. (U.S. patent #6,143,247) or Buechler (U. S. Patent #5,458,852) in view of Van Deusen et al. (U.S. Patent #5,132,097) in further view of Slovacek et al. (U.S. Patent#5,242,837) are set forth above. However, these references fail to teach the assay as a kit.

Zuk et al. (4,281,061) teach that "as a matter of convenience the reagents [of an immunoassay] can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest" (column 22, lines 63-66).

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It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay device as taught by Sheppard et al. (U.S. patent #6,143,247) or Buechler (U. S. Patent #5,458,852) in view of Van Deusen et al. (U.S. Patent #5,132,097) in further view of Slovacek et al. (U.S. Patent#5,242,837) and format it into a kit because Zuk et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Although the reference does not specifically disclose that a kit would have instructions which teach how to use said kit, it would have been prima facie obvious to any one of ordinary skill in the art to include instructions which describe how to perform the assay. Applicants should note that the printed matter on the instructions in a kit cannot serve to define the kit over the prior art. See in re Gulack 217 USPQ (CAFC 1983).

Response to Arguments

15. In response to the argument that Buechler (U. S. Patent #5,458,852) or Sheppard et al. (U.S. patent #6,143,247) do not teach the conversion of optical signals to electronic measurements for subsequent analysis, it is noted that the new reference of Van Deusen et al. (U.S. Patent #5,132,097). Regarding the limitations concerning diagnostic lane configurations the primary references disclose these embodiments as supported by applicant in the disclosure on on page 59, lines 21-28.

With respect to the arguments Van Deusen et al. (U.S. Patent #5,132,097), Slovacek et al. (U.S. Patent#5,242,837), and Zuk et al. (U.S. Patent#4,281,061); they have been readdressed with the Van Deusen et al. (U.S. Patent #5,132,097) rejection.

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16. For reasons aforementioned, no claims are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. See MPEP § 706.07(a).

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 29 February 2000 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Lisa V. Cook
CM1-7B17
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2/25/02



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02/25/02